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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,797	02/27/2004	02/27/2004 Patrick Miles 014  06/16/2006  gler, Esq.  oad  131  /// 2 6 2006  ART	014US1	9437
75	590 06/16/2006	1PE	EXAM	INER
Jonathan D. S	pangler, Esq.		SMITH, STE	PHANIE R
San Diego, CA	· · · · · · · · · · · · · · · · · · ·	[ S 2006 ]	ART UNIT	PAPER NUMBER
			3762	
	" William		DATE MAILED: 06/16/2006	5
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Please find below and/or attached an Office communication concerning this application or proceeding.

BEST AVAILABLE COPY

	Application No.	Applicant(s)
	10/789,797	MILES ET AL.
Office Action Summary	Examiner	Art Unit
	Stephanie Smith	3762
The MAILING DATE of this communication app	ears on the cover sheet with the c	orrespondence address
Period for Reply	VIS SET TO EXPIRE 3 MONTH(	S) OR THIRTY (30) DAYS
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DOWN THE MAILING DOWN THE MAILING DOWN THE MAILING DOWN THE MEDICAL STATE OF TH	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE!	l. ely filed the mailing date of this communication. () (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 27 Fe	ebruary 2004.	
2a) ☐ This action is <b>FINAL</b> . 2b) ☑ This	action is non-final.	
3) Since this application is in condition for allowa	nce except for formal matters, pro	secution as to the merits is
closed in accordance with the practice under E	Ex parte Quayle, 1935 C.D. 11, 45	3 O.G. 213.
Disposition of Claims		
4) Claim(s) 1-19 is/are pending in the application		•
4a) Of the above claim(s) is/are withdra	wn from consideration.	
5), Claim(s) is/are allowed.		
6) Claim(s) <u>1-19</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and/o	r election requirement.	
Application Papers		
9) ☐ The specification is objected to by the Examine	er	
10)⊠ The drawing(s) filed on <u>27 February 2004</u> is/ar	e: a)⊠ accepted or b)⊡ objecte	d to by the Examiner.
Applicant may not request that any objection to the	drawing(s) be held in abeyance. See	e 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correct	tion is required if the drawing(s) is ob	jected to. See 37 CFR 1.121(d).
11) The oath or declaration is objected to by the Ex	xaminer. Note the attached Office	Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign	n priority under 35 U.S.C. § 119(a	)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:		
<ol> <li>Certified copies of the priority document</li> </ol>	ts have been received.	
2. Certified copies of the priority document	ts have been received in Applicat	on No
3. Copies of the certified copies of the price	ority documents have been receive	ed in this National Stage
application from the International Burea	u (PCT Rule 17.2(a)).	
* See the attached detailed Office action for a list	of the certified copies not receive	<b>20</b>
Attachment(s)	4) Interview Summary	(PTO-413)
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> </ol>	Paper No(s)/Mail D	ate
3) X Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08	) 5) Notice of Informal F 6) Other:	Patent Application (PTO-152)
Paper No(s)/Mail Date 30 July 2004. 33 May 2005	0, <u>.</u> . 5	

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#### **DETAILED ACTION**

#### Information Disclosure Statement

The information disclosure statements (IDSs) submitted on July 30, 2004 and May 23, 2005 were filed after the mailing date of the application on February 27, 2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 9, 15, 17-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Koros et al (U.S. 5928139). Referring to claims 1 and 15, Koros et al. teach a distraction and retraction system for creating a corridor to the spine (see figures 1 and 4 and column 2, lines 43-47 and column 6, lines 42-53). Koros et al. further teach that the retractor system is received within the distraction corridor, where corridor is defined as a passageway, and the system has a plurality of blades simultaneously introduced into the corridor and are dimensioned to be simultaneously opened to create a corridor to the surgical site (see figures 1 and 4 and column 2, lines 65-67; column 3, lines 1-8 and lines 12-17; and column 4, lines 23-28). Referring to claim 4, Koros et al. teach a plurality of arm members integrally formed together with a respective one of

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said plurality of retractor blades (see figure 1 and column 5, lines 29-45), where any of the arms can be used as a handle. Referring to claim 9, Koros et al. teach that this apparatus is configured to access a spinal target site (see figures 4 and 5 and column 2, lines 43-45). Referring to claims 17 and 18, Koros et al. teach that when the retractor blades are introduced into the spinal area, at least one shim element, in this case a screw, is detachably engaged with at least one of the retractor blades (see figures 3 and 5 and column 3, lines 10-12).

Claims 1, 5-7, 12, 14-15, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Desai (U.S. 2002/0010392). Referring to claims 1 and 15, Desai teaches a retraction system with blades that can be opened to create an operative corridor to the target site, the blades being comprised of the ablation catheter (see page 3, paragraph 59, page 4, paragraph 61, and page 8, paragraphs 118-120). Referring to claims 5 and 14, Desai teaches a system for cardiac ablation that includes a multi-electrode catheter (see page 4, paragraph 65). Referring to claims 6-7 and 19, Desai teaches a computer that controls the various functional components of the mapping unit, and the electrogram signals emanated from a tachycardia site of origin are detectable by the electrode array, and the arrival times of sensed electrical activity are used to map the origin of a tachycardia (see page 2, paragraphs 26-29). Further, Desai teaches instructing stimulation of the heart to pick up arrival times to determine the direction and origin of activity and map the activity (see page 5, paragraph 81). Regarding claim 12, the control unit includes a display to display an electrocardiogram of the muscle (see pages 3 and 4, paragraph 60).

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## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2, 3, 8, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. in view of Weiner (U.S. 2003/0225405). Koros et al. teach the apparatus described above, but do not teach using a K-wire and at least one dilator to perform distraction. Weiner teaches using K-wire for distraction and further teaches that it is well known in the art to use K-wire for distraction (see page 1, paragraph 17). Weiner further teaches that the K-wires extend through clamp openings (see page 2, paragraph 17), the clamp being a dilator because it can dilate a cavity or orifice. A clamp is a desirable dilator because it is rigid and adjustable. Regarding claim 3, Koros et al. teach the shim element as described above. Therefore, it would

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have been obvious to one of ordinary skill in the art at the time the invention was disclosed to combine the distraction and retraction system taught by Koros et al. with a the K-wire and clamp because it is well known in the art and because it is adjustable yet provides support.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al in view of as applied to claim 2 above, and further in view of Desai. Koros et al. in view of Weiner teach the apparatus described above; but do not teach placing a stimulation electrode at the tip of the K-wire. Desai teaches placing stimulation electrodes at the end of a catheter array (see page 4, paragraphs 66-68). Desai teaches that these electrodes provide accurate guidance (see page 2, paragraph 24). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was disclosed to combine the apparatus taught by Koros et al. in view of Weiner with the electrode taught by Desai in order to provide accurate guidance.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. in view of Dietz (U.S. 6126660). Koros et al. teach the apparatus described above, but do not teach a lateral, trans-psoas approach. Dietz does teach a lateral, trans-psoas approach and that this is an approach used often (see column 10, lines 27-31). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to combine the apparatus taught by Koros et al. with using a lateral trans-psoas approach because it is common to use such an approach in distraction.

Claims 11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koros et al. and Desai as applied to claim 6 above, and further in view of Dabney

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et al (U.S. 6620157). Koros et al. in view of Desai teach the apparatus described above, but do not teach the button on the handle to initiate stimulation or the touch-screen. Dabney et al. do teach the button on the handle to initiate stimulation or the touch-screen (see column 7, lines 1-13). A button on the handle allows the user to easily and quickly provide stimulation and the touch screen also allows a user to quickly and easily select options. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the apparatus taught by Koros et al. in view of Desai with a button to provide stimulation and a touch-screen in order to allow the user to quickly and easily perform therapy or select options.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Smith whose telephone number is 571-272-2834. The examiner can normally be reached on Monday-Friday between 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

585 6/12/2006 SRS

GEORGE R. EVANISKO PRIMARY EXAMINER

#### Applicant(s)/Patent Under Application/Control No. Reexamination 10/789,797 MILES ET AL. Notice of References Cited Art Unit Examiner Page 1 of 1 3762 Stephanie Smith U.S. PATENT DOCUMENTS **Document Number** Date Classification Name Country Code-Number-Kind Code MM-YYYY 606/54 Weiner, Lon S. 12-2003 US-2003/0225405 606/61 10-2000 Dietz, John W. \* US-6,126,660 В 600/374 01-2002 Desai, Jawahar M. \* US-2002/0010392 С 606/34 \* 09-2003 Dabney et al. US-6,620,157 D US-Ε US-F US-G US-Н US-US-J US-Κ US-L US-М FOREIGN PATENT DOCUMENTS **Document Number** Date Classification Name Country Country Code-Number-Kind Code MM-YYYY N 0 Р Q R S Т NON-PATENT DOCUMENTS Include as applicable: Author, Title Date, Publisher, Edition or Volume, Pertinent Pages) U W

\*A copy of this reference is not being furnished with this Office action. (See MPEP § 707.05(a).) Dates in MM-YYYY format are publication dates. Classifications may be US or foreign.

Substitute for form 1449A/PTO
INFORMATION DISCLOSURE STATEMENT BY APPLIF (Use as many sheets as necessary) TRADEN

<b>Application Number</b>	10/789,797	
Filing Date	February 27, 2004	
First Named Inventor	Miles, Patrick	
Group Art Unit	Unknown	
Examiner Name	Unknown	

Sheet 1 of 5

Attorney Docket No: 80100.014US1

			ATENT DOCUMENT		Cubalana	Filing Date
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	If Appropriate
SS	US- 2002/0007129 A1	01/17/2002	Marino, J. F.	600	546	06/08/2001
	US- 2002/0072686 A1	06/13/2002	Hoey, M. , et al.	600°	547	05/18/2001
	US-2,704,064	03/15/1955	Fizzell, J. A., et al.	128	2.1	09/10/1952
	US-3,364,929	01/23/1968	Ide, W. S., et al.	128	172.1	12/21/1964
	US-3,664,329	05/23/1972	Naylor, R. N.	128	2.1 R	03/09/1970
	US-3,682,162	08/08/1972	Colyer, J. E.	128	2.1 R	12/04/1969
	US-3,785,368	01/15/1974	McCarthy, T. M., et al.	128	2.1 Z	08/23/1971
$\dashv$	US-3.830,226	08/20/1974	Staub, D. E., et al.	128	2.1 R	06/15/1973
	US-3,957,036	05/18/1976	Normann, N. A.	128	2.1 R	02/03/1975
	US-4,099,519	07/11/1978	Warren, F. E.	128	2.1 R	01/14/1977
	US-4,207,897	06/17/1980	Lloyd, J. W., et al.	128	303.1	07/13/1977
	US-4,224,949	09/30/1980	Scott, Norman R., et al.	128	734	11/17/1977
	US-4,235,242	11/25/1980	Howson, David C., et al.	128	695	04/02/1979
_	US-4,285,347	08/25/1981	Hess, S. R.	128	785	07/25/1979
	US-4,291,705	09/29/1981	Severinghaus, John W., et al.	600	546	09/10/1979
	US-4,515,168	05/07/1985	Chester, M. H., et al.	128	741	07/22/1983
	US-4,519,403	05/28/1985	Dickhudt, E. A.	128	785	04/29/1983
-+	US-4,545,374	10/08/1985	Jacobson, R. E.			09/03/1982
	US-4,561,445	12/31/1985	Berke, Joseph, et al.	128	642	05/25/1983
	US-4,592,369	06/03/1986	Davis, Graham R., et al.	128	733	07/08/1983
-	US-4,595,018	06/17/1986	Rantala, B.	128	733	06/06/1984
	US-4,633,889	01/06/1987	Talalla, A.	128	784	12/12/1984
	US-4,658,835	04/21/1987	Pohndorf, P. J.	128	785	07/25/1985
	US-4,744,371	05/17/1988	Harris, D. L.	607	117	04/27/1987
	US-4,759,377	07/26/1988	Dykstra, Dennis D.	128	733	11/26/1986
	US-4,807,642	02/28/1989	Brown, David A.	128	733	04/10/1987
_	US-4,892,105	01/09/1990	Prass, R. L.	128	741	01/11/1988
	US-4,926,865	05/22/1990	Oman, P. S.	128	421	01/17/1989
	US-4,962,766	10/16/1990	Herzon, G. D.	128	741	07/19/1989
V	US-4,964,411	10/23/1990	Johnson, Michael T., et al.	128	733	07/13/1989

**EXAMINER** 

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED

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Approved for use through 1051/2002 OMB 651-0031
US Patent & Tradmark Office U.S. DEPARTMENT OF COMMERCE
on of Information unless 1 Contains a valid Child review in any

Substitute for form 1449A/PTO	Complete If Known	
INFORMATION DISCLOSURE	<b>Application Number</b>	10/789,797
STATEMENT BY APPLICANT (Use as many sheets as necessary)	Filing Date	February 27, 2004
	First Named Inventor	Miles, Patrick
	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 2 of 5	Attorney Docket No: 8	30100.014US1

SS	US-5,007,902	04/16/1991	Witt, H.	604	117	02/22/1989
35	US-5,058,602	10/22/1991	Brody, Stanley R.	128	733	10/04/1989
	US-5,081,990	01/21/1992	Deletis, Vedran	128	642	05/11/1990
<b></b>	US-5,092,344	03/03/1992	Lee, T.	128	741	11/19/1990
<b>  -</b>	US-5,127,403	07/07/1992	Brownlee, Robert R.	128	419 P	08/21/1990
	US-5,161,533	11/10/1992	Prass, Richard L., et al.	128	639	09/19/1991
	US-5,196,015	03/23/1993	Neubardt, Seth L.	606	61	04/30/1992
<b></b>	US-5,255,691	10/26/1993	Otten, L. M.	607	117	11/13/1991
<del>   -</del>	US-5,282,468	02/01/1994	Klepinski, R. J.	128	642	01/08/1992
	US-5,284,153	02/08/1994	Raymond, S. A., et al.	128	741	04/14/1992
	US-5,284,154	02/08/1994	Raymond, S. A., et al.	128	741	10/23/1992
	US-5,312,417	05/17/1994	Wilk, Peter	606	114	07/29/1992
	US-5,313,956	05/24/1994	Knutsson, E., et al.	128	741	08/04/1992
<del></del>	US-5,327,902	07/12/1994	Lemmen, R. D.	128	734	05/14/1993
<del>                                     </del>	US-5,333,618	08/02/1994	Lekhtman, G., et al.	128	734	06/30/1993
<del></del>	US-5,375,067	12/20/1994	Berchin, G. J.	364	487	12/11/1992
	US-5,383,876	01/24/1995	Nardella, Paul	606	49	03/22/1994
	US-5,474,558	12/12/1995	Neubardt, S. L.	606	79	07/18/1994
<b></b>	US-5,482,038	01/09/1996	Ruff, L. H.	128	642	06/28/1994
	US-5,540,235	07/30/1996	Wilson, J. R.	128	741	06/30/1994
	US-5,549,656	08/27/1996	Reiss, H. W.	607	48	05/15/1995
	US-5,560,372	10/01/1996	Cory, P. C.	128	741	02/02/1994
-	US-5,566,678	10/22/1996	Cadwell, J. A.	128	731	01/05/1995
	US-5,579,781	12/03/1996	Cooke, Thomas H.	128	733	10/13/1994
<del>    -</del>	US-5,593,429	01/14/1997	Ruff, L. H.	607	116	06/28/1994
<del></del>	US-5,630,813	05/20/1997	Kieturakis, M. J.	606	46	12/08/1994
	US-5,671,752	09/30/1997	Sinderby, Christer, et al.	128	733	03/31/1995
<b> </b>	US-5,707,359	01/13/1998	Bufalini, Bruno	604	104	11/14/1995
<b></b>	US-5,711,307	01/27/1998	Smits, Matthijs P.	128-	733	04/13/1995
	US-5,775,331	07/07/1998	Raymond, S. A., et al.	128	741	06/07/1995
	US-5,779,642	04/14/1998	Nightengale, Christopher	600	461	02/18/1997
	US-5,797,854	08/25/1998	Hedgecock, J. L.	600	554	08/01/1995
	US-5,814,073	09/29/1998	Bonutti, Peter	606	232	12/13/1996
	US-5,830,151	11/03/1998	Hadzic, A., et al.	600	554	11/26/1997
	US-5,851,191	12/22/1998	Gozani, S. N.	600	554	07/01/1997
1	US-5,853,373	12/29/1998	Griffith, R. L., et al.	600	554	08/05/1996
W-	US-5,885,219	03/23/1999	Nightengale, C.	600	461	10/21/1997

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED 06/08/2006

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Substitute for form 1449A/PTO	Complete if Known	
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	Group Art Unit	Unknown
	Examiner Name	Unknown
Sheet 3 of 5	Attorney Docket No: 8	30100.014US1

	LIO F 000 400	03/30/1999	Bonutti, Peter M.	600	204	06/05/1995
SS	US-5,888,196			600	547	03/25/1997
	US-5,928,158	07/01/1999	Aristides, A.		483	02/12/1998
	US-5,976,094	11/02/1999	Gozani, S. N., et al.	600		
	US-6,004,262	12/21/1999	Putz, D. A., et al.	600	114	05/04/1998
	US-6,027,456	02/22/2000	Feler, C. A., et al.	600	554	07/10/1998
	US-6,038,477	03/14/2000	Kayyali, H. A.	607	72	12/23/1998
	US-6,050,992	04/18/2000	Nichols, C.	606	41	05/19/1997
	US-6,104,957	08/15/2000	Alo, K. M., et al.	607	46	08/21/1998
<del> </del>	US-6,132,386	10/17/2000	Gozani, S. N., et al.	600	554	03/16/1999
	US-6,132,387	10/17/2000	Gozani, S. N., et al.	600	554	03/16/1999
<del>                                     </del>	US-6,135,965	10/24/2000	Tumer, K., et al.	600	476	12/02/1996
	US-6,146,335	11/14/2000	Gozani, S. N.	600	554	03/16/1999
-	US-6,161,047	12/12/2000	King, G. W., et al.	607	62	04/30/1998
<del>                                     </del>	US-6,224,549	05/01/2001	Drongelen, W. V.	600	300	04/20/1999
<b></b>	US-6,259,945	07/10/2001	Epstein, R., et al.	600	547	04/30/1999
	US-6,266,558	07/24/2001	Gozani, Shai N., et al.	600	547	12/01/1998
	US-6,292,701	09/01/2001	Prass, R. L., et al.	607	116	07/29/1999
	US-6,312,392	11/01/2001	Herzon, G. D.	600	554	04/06/2000
<del>                                     </del>	US-6,466,817	10/01/2002	Kaula, N. F., et al.	600	546	06/08/2000
<del>    -   -   -   -   -   -   -   -   -  </del>	US-6,500,128	12/31/2002	Marino, J. F.	600	554	06/08/2001
<b>\</b>	US-6,564,078	05/13/2003	Marino, J. F., et al.	600	373	06/04/1999
$\vdash \!\!\!\! \! \!\!\!\!\! \!$	US-R.E34,390	09/28/1993	Culver, N. D.	128	731	02/28/1991

		<b>FOREIGN PATENT</b>	DOCUMENTS			
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Class	Subclass	T2
SS	WO-0066217A1	11/09/2000	Epstein, R., et al.	A61N	1/36	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
SS	***	"Electromyography System", International Search Report, International Application No. PCT/US00/32329,(April 27, 2001),9 pages	
		"Nerve Proximity and Status Detection System and Method", International Search Report, International Application No. PCT/US01/18606,(October 18, 2001),6 pages	
		"Relative Nerve Movement and Status Detection System and Method",  International Search Report, International Application No.  PCT/USO1/18579 (January 15, 2002),6 pages	
$\bigvee$		"System and Method for Determining Nerve Proximity, Direction, and Pathology During Surgery", International Search Report, International Application No. PCT/US02/22247, (March 27, 2003), 4 pages	

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED

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INFORMATION DISCLOSURE	Application Number	10/789,797				
STATEMENT BY APPLICANT (Use as many sheets as necessary)	Filing Date	February 27, 2004				
	First Named Inventor	Miles, Patrick				
	Group Art Unit	Unknown				
	Examiner Name	Unknown				
740	Attorney Docket No: 8	30100.014US1				
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	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	T
Examiner initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Ľ
		"System and Methods for Determining Nerve Direction to a Surgical	
ss		Instrument", International Search Report, International Application No.	
		PCT/US03/02056.(August 12, 2003),5 pages	
		"Systems and Methods for Performing Percutaneous Pedicle Integrity	
		Assessments", International Search Report, International Application No.	1
		PCT/US02/35047,(August 11, 2003),5 pages	
		"Systems and Methods for Performing Surgery Procedures and Assessments",	
		International Search Report, International Application No.	
1 1		PCT/US02/30617,(June 5, 2003),4 pages	
		BOSE, et al., "Neurophysiologic Monitoring of Spinal Nerve Root Function	
i i	i	During Instrumented Posterior Lumbar Spine Surgery", Spine, 27(13).	
1 1			
_		(2002),1444-1450  CALANCIE, et al., "Stimulus-Evoked EMG Monitoring During Transpedicular	1
		CALANCIE, et al., "Stimulus-Evokeu Eing Monitoring During Transpedicular	
		Lumbosacral Spine Instrumentation", Spine, 19(24), (1994),2780-2786	╁
\		CLEMENTS, et al., "Evoked and Spontaneous Electromyography to Evaluate	
		Lumbosacral Pedicle Screw Placement", Spine, 21(5), (1996),600-604	╀╌
		FORD, et al., "Electrical Characteristics of Peripheral Nerve Stimulators	
1		Implications for Nerve Localization", Regional Anesthesia, 9, (1984),73-77	╁
		GLASSMAN, et al., "A Prospective Analysis of Intraoperative Electromyographic	
		Monitoring of Pedicle Screw Placement With Computed Tomographic Scan	
		Confirmation" Spine 20(12) (1995) 1375-1379	↓_
		GREENBLATT, et al., "Needle Nerve Stimulator-Locator: Nerve Blocks with a	
		New Instrument for Locating Nerves", Anesthesia & Analgesia, 41(5),	
	ł	(1962) 599-602	1
		HOLLAND, N., "Intraoperative Electromyography During Thoracolumbar Spinal	
		Surgery <sup>®</sup> Spine 23(17) (1998).1915-1922	丄
		LENKE, et al., "Triggered Electromyographic Threshold for Accuracy of Pedicle	
		Screw Placement", Spine, 20 (14), (1995), 1585-1591	
		MAGUIRE, et al., "Evaluation of Intrapedicular Screw Position Using	T
		Intraoperative Evoked Electromyography", Spine, 20(9), (1995),1068-1074	
		MARTIN, et al., "Initiation of Erection and Semen Release by Rectal Probe	T
		Electrostimulation (RPE)", The Williams & Wilkins Co., (1983),637-642	
	<del> </del>	PITHER, et al., "The Use of Peripheral Nerve Stimulators for Regional	1
		Anesthesia: Review of Experimental Characteristics, Technique, and Clinical	1
l.	]	Applications"", Regional Anesthesia, (1985),10:47-53	
		RAJ, et al., "Infraclavicular Brachial Plexus Block - A New Approach",	十
		KAJ, et al., Imitaciaviculai brachiai Piexus Diock - Atten Approach,	
		Anesthesia and Analgesia, (52)6, (1973),897-904  RAJ, et al., "The Use of Peripheral Nerve Stimulators For Regional Anesthesia",	+
1		RAJ, et al., "The Use of Peripheral Nerve Sumulators For Regional Artestiesia",	
<del>  </del>		Clinical Issues In Regional Anesthesia, 1 (4), (1985),1-6	╁╌
V	Į	RAJ, et al., "Use of The nerve Stimulator of Peripheral Blocks", Regional	
		Anesthesia, (apr-jun 1980),14-21	

**EXAMINER** 

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED

Approved for use through 10/31/2002, OMB 651-003

Substitute for form 1449APTO INFORMATION DISCLOSURE	Complete if Known		
	<b>Application Number</b>	10/789,797	
STATEMENT BY APPLICANT Use as many sheets as necessary)	Filing Date	February 27, 2004	
	First Named Inventor	Miles, Patrick	
	Group Art Unit	Unknown	
	Examiner Name	Unknown	
Sheet 5 of 5	Attorney Docket No: 8	30100.014US1	

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner initials*	Cite No 1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
ss		RAYMOND, et al., "The Nerve Seeker: A System for Automated Nerve Localization", Regional Anesthesia, 17(3), (1992),151-162	
1		SHAFIK, "Cavernous Nerve Simulation through an Extrapelvic Subpublic Approach: Role in Pencil Erection", Eur. Urol, 26, (1994),98-102	
V		TOLEIKIS, et al., "The Usefulness of Electrical Stimulation for Assessing Pedicle Screw Replacements", Journal of Spinal Disorder, 13(4), (2000),283-289	

PTO/SB08A(08-03)
Approved for use through 07/31/2008, OMB 0651-0031
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	Group Art Unit	3762	
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		USPA	ATENT DOCUMENT		
Examiner Initial *	USP Document Number	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines,Where Relevant Passage or Relevant Figures Appear	
SS	US-1,548,184	08/04/1925	Cameron, W. J.		
	US- 20050004623A 1	01/06/2005	Miles, P., et al.		
	US- 20050075578A 1	04/07/2005	Gharib, J., et al.		
	US-2,808,826	10/08/1957	Reiner, S., et al.		
	US-4,164,214	08/14/1979	Stark, M. M., et al.		
-	US-4,461,300	07/24/1984	Christensen, J. M.		
-	US-5,480,440	01/02/1996	Kambin, P.		
	US-5,759,159	06/01/1998	Masreliez, C. J.		
	US-5,785,658	07/28/1998	Benaron		
	US-5,862,314	01/19/1999	Jeddeloh		
	US-5,872,314	02/16/1999	Clinton		
_	US-5,928,139	07/27/1999	Koros, T. B.		
	US-6,206,826	03/27/2001	Mathews, H., et al.		
7/	US-6,334,068	12/25/2001	Hacker, D. C.		
<b>-₩</b> -	US-6,760,616	07/06/2004	Hoey, M. F., et al.		

		FOREIGN PATE	ENT DOCUMENTS		
Examiner Initials*	Foreign Document No	Publication Date	Name of Patentee or Applicant of cited Document	Pages,Columns,Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>2</sup>
SS	WO-03037170A3	05/08/2003	Miles, P., et al.		L

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
SS		"Brackmann II EMG System", Medical Electronics, (1999),4 pages	
I		"Neurovision SE Nerve Locator/Monitor", <u>RLN Systems, Inc. Operators Manual</u> , (1999),22 pages	
		"The Brackmann II EMG Monitoring System", Medical Electronics Co.  Operator's Manual Version 1.1, (1995),50 pages	
	<del>                                     </del>	"The Nicolet Viking IV", Nicolet Biomedical Products, (1999),6 pages	
		ANDERSON, D. G., et al., "Pedicle screws with high electrical resistance: a potential source of error with stimulus-evoked EMG", <u>Spine. 27(14):</u> , Department of Orthopaedic Surgery, University of Virginia, (Jul 15, 2002), 1577-1581	
V		DANESH-CLOUGH, T., et al., "The use of evoked EMG in detecting misplaced thoracolumbar pedicle screws", <u>Spine. 26(12)</u> , Orthopaedic Department, Dunedin Hospital,(Jun 15, 2001),1313-1316	

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED

Substitute for form 1449A/PTO	Complete if Known	required to respond to a consection of transmission unjets it consum a valid Calls constituting
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Sheet 2 of 2	Attorney Docket No: 0	14US1

	OTHE	R DOCUMENTS NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No 1	include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T,
SS		DARDEN, B. V., et al., "A comparison of impedance and electromyogram measurements in detecting the presence of pedicle wall breakthrough", <u>Spine.</u> 23(2) Charlotte Spine Center, North Carolina,(Jan 15, 1998),256-262	
		EBRAHEIM, N. A., et al., "Anatomic relations between the lumbar pedicle and the adjacent neural structures", <u>Spine. 22(20)</u> , Department of Orthopaedic Surgery, Medical College of Ohio, (Oct 15, 1997),2338-2341	
		HAIG. "Point of view", Spine 27 (24), 2819	<u> </u>
		HAIG, A. J., et al., "The relation among spinal geometry on MRI, paraspinal electromyographic abnormalities, and age in persons referred for electrodiagnostic testing of low back symptoms", Spine. 27(17), Department of Physical Medicine and Rehabilitation, University of Michigan, (Sep 1, 2002), 1918-1925	
		HOLLAND, N. R., et al., "Higher electrical stimulus intensities are required to activate chronically compressed nerve roots. Implications for intraoperative electromyographic pedicle screw testing", Spine. 23(2), Department of Neurology, Johns Hopkins University School of Medicine, (Jan 15, 1998), 224-227	
$\bigvee$		MINAHAN, R. E., et al., "The effect of neuromuscular blockade on pedicle screw stimulation thresholds", <u>Spine. 25(19)</u> , Department of Neurology, Johns Hopkins University, School of Medicine, (Oct 1, 2000), 2526-2530	

/Stephanie Smith/ (06/08/2006)

DATE CONSIDERED 06/08/2006

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